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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/529,575 | 04/14/2000 | FRANCIS JAMES ROURKE | 7042-R | 9622 |

27752 7590 09/29/2005

THE PROCTER & GAMBLE COMPANY
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EXAMINER

ANDERSON, CATHARINE L

ART UNIT PAPER NUMBER

3761

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,575

Applicant(s)

ROURKE ET AL.

Examiner

C. Lynne Anderson

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30,32,36,41-46 and 48-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,32,36,41-46 and 48-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 May 2005 has been entered.

Response to Arguments

Applicant's arguments filed 23 May 2005 have been fully considered but they are not persuasive.

In response to the applicant's argument that Caldwell's generic teaching of pentamidine as one of many agents suitable for inclusion into a barrier web is insufficient, it is noted that while Caldwell discloses many possible agents for inclusion, since Caldwell explicitly discloses pentamidine, the rejection stands.

In response to the applicant's argument that since Caldwell does not suggest that pentamidine is a protease inhibitor having an IC_{50} of about 500 μ M or less, therefore the property is not inherent to the materials, it is noted that if the prior art teaches the identical chemical structure, the properties the applicant claims are necessarily present (see MPEP 2112.01).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 36, 41-46, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cadwell (5,874,164).

With respect to claims 31, 32, and 36, Cadwell discloses all aspects of the claimed invention but remains silent as to the percent by weight of the protease inhibitor. Cadwell discloses an absorbent article, as described in column 6, lines 23-26, at least a portion of which comprises a protease inhibitor, as described in column 55, lines 16-19. The protease inhibitor is pentamidine, as described in column 55, line 28.

It would have been obvious to one of ordinary skill in the art at the time of invention to have the protease inhibitor present in the article in a range of about 0.0001% to about 30% by weight. The protease inhibitor of Cadwell is coated onto the absorbent article, as disclosed in column 56, lines 15-21, and to coat the surface of the article fully, the amount of protease inhibitor would obviously have to be greater than 0.0001% by weight. However, the surface of the article can only accommodate so much of a coating, and therefore it would also be obvious that the protease inhibitor would not be greater than 30% by weight.

The IC₅₀ is defined in the instant specification on page 7 as being dependant on the concentration of protease inhibitor and the rate of substrate cleavage of the

protease inhibitor. The rate of substrate cleavage is dependent on the individual protease inhibitor, and pentamidine is disclosed in the specification as being a suitable protease inhibitor. Therefore, pentamidine, when present in the claimed concentration, inherently has an IC_{50} of about 500 μM or less, no more than 100 μM , and as a result is capable of producing at least a 10% reduction in substrate hydrolysis by a protease.

With respect to claim 41, the article comprises a delivery system, a barrier web 15, as shown in figure 8, which comprises the protease inhibitor.

With respect to claims 42 and 43, the article can comprise a delivery system, a bandage or surgical gauze, as disclosed in column 53, lines 57-62, which facilitates the healing of a wounds and is therefore a skin care composition. The skin care composition comprises between about 0.0001% and about 30% of the protease inhibitor, as disclosed in the rejection of claim 31 above.

With respect to claim 44, the delivery system is a solid support.

With respect to claim 45, the delivery system is activatable by moisture and releases the protease inhibitor, as disclosed in column 55, lines 31-35.

With respect to claim 46, the delivery system contains the protease inhibitor as molecules, or particles, as disclosed in column 55, line 37.

With respect to claim 48, the article comprises a barrier web 15, as shown in figure 8, having the protease inhibitor disposed on at least a portion thereof. The barrier web 15 comes in contact with the wearer.

With respect to claim 49, the barrier web 15 is part of the waist region of the article, as shown in figure 7.

With respect to claims 50 and 51, the wearer-contacting surface may be a bandage or surgical gauze, as disclosed in column 53, lines 57-62, which is a topsheet.

With respect to claims 52 and 53, it would have been an obvious matter of design choice for the topsheet to comprise regions that do not contain the skin care composition and have the skin care composition disposed in a plurality of stripes, since the applicant has not shown that this application of the skin care composition solves any stated problem or serves any particular purpose, and it appears the invention would perform equally well with the skin care composition disposed on all regions of the topsheet. *In re Dailey*, 140 USPQ 47.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CMA
cla

September 23, 2005

TATYANA ZALUKAEVA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', with a long, sweeping horizontal line extending to the right.